UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

JOSHUA WILSON, et al. **v.** **LLOYD AUSTIN, in his official capacity as Secretary of the Department of Defense, *et al.***	**Civil Action No. 4:22-cv-438** **Judge Mazzant**

JOINT REPORT OF RULE 26(F) CONFERENCE

The parties jointly, by and through their counsel, respectfully submit the following to the Court in accordance with its order dated May 24, 2023 (ECF 52).

1. A brief factual and legal synopsis of the case.

Plaintiffs' Position

The named Plaintiffs, a diverse group of military servicemembers, both officers and enlisted, filed suit against the Department of Defense ("DoD"), the Armed Services, and the Food and Drug Administration ("FDA") for their joint actions in forcing an unlicensed, experimental, non-vaccine, mRNA gene-therapy shot on the entire American public, including unwitting members of the United States all-volunteer force. The FDA and DoD accomplished this through a layered series of *ultra vires* regulatory acts, which culminated with a Department of Defense official – the Assistant Secretary of Defense for Health Affairs, Ms. Terry Adirim – making the legal determination, in a September 14, 2021 memo, that an unlicensed biological product, Pfizer's emergency use authorization ("EUA") gene-therapy shot BNT162b2, was "interchangeable" with the only FDA-licensed product for "prevention" of COVID-19, Pfizer's Comirnaty®, so that the EUA product should be mandated "as if" it were the actual FDA-licensed product. (On May 3, 2022, Ms. Adirim's successor Seileen Mullen did the same for Moderna, finding that Moderna's EUA COVID-19 gene therapy was legally "interchangeable" with the FDA-licensed SPIKEVAX®.)

These illegal acts have been justified by an FDA official's claim that the FDA exercised its "enforcement discretion" to violate mandatory statutory requirements governing the approval, labeling and sale in interstate commerce of biological products, *inter alia*, to confer the legal status and benefits of licensure on unlicensed products. The DoD went even further by arrogating to itself the

authority to do the same, violating the statutes solely administered by the FDA. As a result, an official in a completely different executive agency than that provided for by Congress now asserts the power to make regulatory decisions regarding biologic products that affects the lives and health of members of the Armed Forces – all in derogation of clear statutory mandates prohibiting such acts by Congress. For just one example, Congress has explicitly reserved the power to mandate EUA products to members of the Armed Forces to only one person in the entire federal government: the President of the United States pursuant to 10 U.S.C. ¶1107a.

Even with rescission of this illegal mandate, the DoD continues to insist on the lawfulness of this regulatory bait-and-switch and, further, that it still retains the authority to punish people who refused to be experimented upon, including some of the Plaintiffs. SSG Steven Brown (for just one example) was prohibited from re-enlisting, punished, and given bad paperwork that he must disclose to civilian employers for pointing out that the DoD had no licensed product and was mandating an unlicensed product by an official with zero authority to do so.

The Plaintiffs seek declaratory and injunctive relief as per their Amended Complaint to remedy these harms and ensure that the DoD officials cannot continue to make licensure decisions for biologic products – aided and abetted by the FDA – in clear violation of the Food Drug and Cosmetic Act's prohibitions on unlicensed products being brought to market – and even forced on unwilling subjects.

Defendants' Position

Fourteen Plaintiffs who serve in the United States Army, Air Force, Navy, or Marine Corps, along with an unincorporated association, sued on behalf of themselves and a putative class the Secretary of Defense, the Commissioner of the Food and Drug Administration ("FDA"), and the Secretary of the Department of Health and Human Services, each solely in their official capacity. Plaintiffs allege that the military's rescinded COVID-19 vaccination requirement violates (i) the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 ("NDAA"); (ii) the Administrative Procedure Act ("APA"); (iii) 10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3; and (iv) the equal-protection component of the Fifth Amendment. They also assert claims against FDA for alleged statutory violations.

2. The jurisdictional basis for this suit.

Plaintiffs' Position

Jurisdiction is proper in this Court because the federal district courts are the sole place for a citizen to vindicate their rights as against the regulatory decisions of unelected government officials through the Administrative Procedure Act

("APA") and Constitutional claims. Plaintiffs assert both in this case. Injunctive and declaratory relief frequently go hand-in-glove. Suits challenging the DoD and the FDA's *ultra vires* regulatory acts are quintessentially a matter for federal district courts.

Defendants' Position

This Court lacks jurisdiction because this case is moot, as the military has rescinded its COVID-19 vaccination requirement pursuant to the NDAA. But even setting mootness aside, this Court would lack jurisdiction for the following additional reasons:

- Plaintiffs lack Article III standing to assert claims under 10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3 because each Plaintiff was able to comply with the military's now-rescinded COVID-19 vaccination requirement by receiving available doses of Comirnaty.
- Plaintiffs lack Article III standing to assert their claims against the FDA because they have alleged no injury fairly traceable to the FDA's actions or that could be redressed by an order against the FDA.
- The Members of the Armed Forces for Liberty lacks Article III standing to assert claims on behalf of its so-called "members."

3. A list of the correct names of the parties to this action and any anticipated additional or potential parties.

Plaintiffs are Joshua Wilson, Thomas Blankenship, Steven Brown, Karyn Christen, Michael Doughty, Summer Fields, Derrick Gibson, Carley Gross, Michael Groothousen, Justin King, Ryan Madigan, Brittany Puckett, Benjamin Walker, Scott Wells, and Members of the Armed Forces for Liberty (an unincorporated association). Defendants are Secretary of Defense Lloyd Austin III, Commissioner of Food and Drugs Robert Califf, and Secretary of the Department of Health and Human Services Xavier Becerra, each acting solely in their official capacity. No additional parties are anticipated to join this action.

4. A list of any cases related to this case pending in any state or federal court, identifying the case numbers and courts along with an explanation of the status of those cases.

Plaintiffs' Position

While there have been numerous cases involving military plaintiffs and the DoD over the vaccine mandate, very few involved challenges to FDA actions that enabled it. Therefore, given the centrality of the FDA in this litigation, Plaintiffs have included only those cases that included the FDA as a defendant.

- *Coker, et al. v. Austin, et al.,* No. 3:21-cv-1211 (N.D. Fla.)
- *Robert et al v. Austin, et al.*, No. 1:21-cv-2228 (D. Co.)(on appeal to the 10th Cir, No. 22-1032).

Defendants' Position

The following cases challenge the military's now-rescinded COVID-19 vaccination requirement:

- *Abbott v. Biden*, No. 6:22-cv-3 (E.D. Tex.)
  - Interlocutory appeal, No. 22-40399 (5th Cir.)
- *Air Force Off. v. Austin*, No. 5:22-cv-9 (M.D. Ga.)
  - Interlocutory appeal, No. 22-11200 (11th Cir.)
- *Alvarado v. Austin*, No. 23-1419 (4th Cir.)
- *Coker v. Austin*, No. 3:21-cv-1211 (N.D. Fla.)
- *Davis v. Austin*, No. 3:22-cv-237 (M.D. Fla.)
- *Doster v. Kendall*, No. 1:22-cv-84 (S.D. Ohio)
- *Galey v. Biden*, No. 2:22-cv-06203 (W.D. La.)
- *Jackson v. Mayorkas*, No. 4:22-cv-825 (N.D. Tex.)
- *Navy SEALs 1–3 v. Austin*, No. 4:21-cv-1236 (N.D. Tex.)
  - Interlocutory appeal, No. 22-10534 (5th Cir.)
- *Poffenbarger v. Kendall*, No. 3:22-cv-1 (S.D. Ohio)
- *Robert v. Austin*, No. 22-01032 (10th Cir.)
- *Rudometkin v. Austin*, No. 1:21-cv-2220 (D.D.C.)
- *Schelske v. Austin*, No. 6:22-cv-49 (N.D. Tex.)
- *Schneider v. Austin*, No. 3:22-cv-293 (S.D. Tex.)
- *Spence v. Austin*, No. 4:22-cv-453 (N.D. Tex.)
- *Bassen v. United States*, No. 23-174C (Fed. Cl.)
- *Botello v. United States*, No. 23-211C (Fed. Cl.)
- *Wiese v. Biden*, No. 3:22-cv-01458 (S.D. Ill.)

The following cases challenged the military's now-rescinded COVID-19 vaccination requirement but have since been dismissed on various grounds, including after denials of requests for preliminary injunctive relief or for mootness:

- *Air Force Major v. Austin*, No. 3:22-cv-00756 (N.D. Tex.)
- *Bazzrea v. Mayorkas*, No. 3:22-cv-265 (S.D. Tex.)
- *Chancey v. Biden*, No. 1:22-cv-110 (N.D. Fla.)
- *Costin v. Biden*, No. 21-2484 (D.D.C.)
- *Clements v. Austin*, No. 2:22-cv-2069 (D.S.C.)

- *Col. Fin. Mgmt. Off. v. Austin*, No. 8:22-cv-1275 (M.D. Fla.)
- *Creaghan v. Austin*, No. 1:22-cv-981 (D.D.C.)
  - Appeal, No. 23-5101 (D.C. Cir.)
- *Crocker v. Austin*, No. 5:22-cv-757 (W.D. La.)
- *Crosby v. Austin*, No. 8:21-cv-02730 (M.D. Fla.)
- *Dunn v. Austin*, No. 2:22-cv-288 (E.D. Cal.)
- *Knick v. Austin*, No. 1:22-cv-01267 (D.D.C.)
- *Miller v. Austin*, No. 2:22-cv-00118 (D. Wyo.)
- *Navy SEAL 1 v. Austin*, No. 1:22-cv-688 (D.D.C.)
- *Navy SEAL 1 v. Austin*, No. 8:21-cv-2429 (M.D. Fla.)
- *Oklahoma v. Biden*, No. 5:21-cv-01136 (W.D. Okla.)
- *Pilot v. Austin*, No. 8:22-cv-1278 (M.D. Fla.)
- *Roberts v. Roth*, No. 1:21-cv-01797 (D.D.C.)
- *Roth v. Austin*, No. 8:22-cv-3038 (D. Neb.)
- *Short v. Berger*, No. 22-16607 (9th Cir.)
- *Vance v. Wormuth*, No 3:21-cv-00730 (W.D. Ken.)

5. Confirm that initial mandatory disclosure required by Rule 26(a)(1) and this order has been completed.

The parties exchanged initial mandatory disclosures on June 26, 2023.

6. Proposed scheduling order deadlines.

Plaintiffs' Position

Plaintiffs' Position is to use the standard deadlines in Appendix I of the Court's Order.

Defendants' Position

Defendants currently have a motion to dismiss pending before the Court, the resolution of which may obviate the need for any further proceedings in this matter or, at a minimum, will help to define the scope of the issues that will need to be resolved through further proceedings. Accordingly, Defendants respectfully suggest that the Court wait to establish any further scheduling deadlines until after it resolves Defendants' motion to dismiss. *See, e.g.*, *Petrus v. Bowen*, 833 F.2d 581, 583 (5th Cir. 1987) (holding "that the district court properly deferred discovery" while considering a motion to dismiss, and explaining that a "trial court has broad discretion and inherent power to stay discovery until preliminary questions that may dispose of the case are determined"); *Roberts v. FNB South of Alma*, 716 F. App'x 854, 857 (11th Cir. 2017) ("District courts enjoy broad discretion in deciding how best to manage the cases before them. And, in general, motions to dismiss for

failure to state a claim should be resolved before discovery begins." (cleaned up)); *Stollings v. Tex. Tech Univ.*, 2021 WL 4171815, at *2 (N.D. Tex. Apr. 13, 2021) (finding it appropriate to stay discovery pending resolution of a motion to dismiss on threshold grounds because, "[i]f defendants must respond to discovery now and the [m]otion to [d]ismiss is later granted, resources will have been expended needlessly" (cleaned up)). Alternatively, if the Court would prefer to establish a schedule before resolution of that motion, Defendants submit that the scheduling deadlines reflected in Appendix 1 of the Court's Order Governing Proceedings, ECF No. 52 at 8–10, run from the date on which the Court resolves Defendants' motion to dismiss rather than from the date of the Court's case management conference.

7. Describe in accordance with Rule 26(f):

(i) The subjects on which discovery may be needed, when discovery should be completed, and whether discovery should be conducted in phases or be limited to or focused on particular issues.

Plaintiffs' Position

Consistent with Plaintiffs' Sur-Reply to the Government's Motion to Dismiss, Plaintiffs believe that the Court cannot decide some of the claims without an administrative record. (ECF 53, p. 6). Therefore, Plaintiffs believe that the government must provide the administrative record for the Court to rule on the APA related claims.

Plaintiffs will seek additional discovery beyond the publicly available documents already relied upon in this case to include any non-public documents or approvals, classified or unclassified, relevant to the proving Plaintiffs' claims, including but not limited to evidence regarding: (1) the DoD's mandate of unlicensed, EUA products; (2) the DoD purported authority to mandate unlicensed, EUA products; (3) DoD officials' purported authority to regulate biologic products; (4) DoD officials' determination that an unlicensed, EUA product is "interchangeable" with an FDA-licensed product; (5) FDA officials' determination that an unlicensed product is "interchangeable" with an FDA-licensed product; (6) FDA officials' exercise of "enforcement discretion" to ignore or waive mandatory statutory requirements governing approval, labeling, and misbranding of unlicensed COVID-19 products; (7) any and all instances prior to the instant one in which the FDA has allowed DoD officials to govern the interchangeability of biologics; (8) any other agencies that claim to have the authority regulate biologic products or to determine that an unlicensed product is "interchangeable" with an FDA licensed product; and (9) any previous instances in which the FDA has exercised its statutory authority under the Public Health Service Act to find that a

biologic product is "interchangeable" with an FDA-licensed product and the procedures and standards used by Defendant FDA in those instances.

Defendants' Position

No discovery is necessary in this case because this case is moot. Moreover, even if the Court reaches the merits of Plaintiffs' claims that are explicitly pled under the APA or should be decided thereunder (*i.e.*, Counts I–XIII, X), Defendants submit that these claims should be resolved solely on the basis of the administrative record, without discovery. *See* Fed. R. Civ. P. 26(a)(1)(B), (f)(1) (exempting administrative-record cases from Rule 26 requirements).

In the event that discovery proceeds on Plaintiffs' equal-protection claim (Count IX), however, Defendants would plan to conduct discovery on, *inter alia*, (i) Plaintiffs' alleged injuries, (ii) past application of DoD's and the Services' now-rescinded COVID-19 vaccination requirements to each Plaintiff, and (iii) Plaintiffs' allegations of current disparate treatment.

(ii) Any issues relating to disclosure or discovery of electronically stored information ("ESI"), including the form or forms in which it should be produced (whether native or some other reasonably usable format) as well as any methodologies for identifying or culling the relevant and discoverable ESI. Any disputes regarding ESI that counsel for the parties are unable to resolve during conference must be identified in the report.

At this time, the parties do not anticipate that any electronic discovery issues will arise in this matter and are discussing the possibility of a stipulation regarding electronically stored information ("ESI"). Thus far, the parties have agreed that the format of any production will be text-searchable PDFs without any accompanying metadata. Should any party request metadata for any particular document, parties will confer to determine if the request is proportional to the needs of the case pursuant to Fed. R. Civ. P. 26. If an issue does arise, however, the parties agree to work in good faith to resolve the matter before bringing the issue to the Court's attention.

(iii) Any agreements or disputes relating to asserting claims of privilege or preserving discoverable information, including electronically stored information and any agreements reached under Federal Rule of Evidence 502 (such as the potential need for a protective order and any procedures to which the parties might agree for handling inadvertent production of privileged

information and other privilege waiver issues). A party asserting that any information is confidential should immediately apply to the Court for entry of a protective order.

The parties are currently negotiating a protective order to implement Fed. R. Evid. 502(d). Should the parties reach an agreement, they will file the proposed order with the Court. Should any discovery include confidential or sensitive information, including information protected from disclosure under the Privacy Act, the parties will jointly propose a protective order covering such information.

(iv) Any changes that should be made in the limitations on discovery imposed by the Rules, whether federal or local, and any other limitations that should be imposed, as well as

None.

(v) Whether any other orders should be entered by the Court pursuant to Federal Rule of Civil Procedure 26(c) or 16(b), (c)

None.

8. State the progress made toward settlement, and the present status of settlement negotiations, including whether a demand and offer has been made. If the parties would like to suggest a mediator, also state the name, address, and phone number of that mediator, and a proposed deadline for mediation. An early date is encouraged to reduce expenses.

Plaintiffs' Position

Settlement is unlikely given the parties' positions and the fact that Plaintiffs' claims for declaratory and injunctive relief.

Defendants' Position

Defendants do not think that this case can be settled at this time.

9. The identity of persons expected to be deposed.

Plaintiffs' Position

Peter Marks, Terry Adirim, Seileen Mullen, Tonya Rans, and any other DoD or FDA officials with knowledge about the mandate of unlicensed EUA products

and/or the interchangeability findings and directives. Plaintiffs will also seek to depose representatives knowledgeable about the shipping logistics and movement of the biologic products from the manufacturing locations to Fort Dietrick, as well as someone knowledgeable about the chain of custody for these biologics through final destinations at Military Treatment Facilities.

Defendants' Position

At this time, Defendants do not expect to depose any individuals because, as explained in their pending motion to dismiss, this case is moot and should be dismissed for lack of subject-matter jurisdiction. Defendants nevertheless reserve their right to depose any Plaintiff or appropriate non-party, as permitted under the Federal Rules of Civil Procedure.

10. Estimated trial time and whether a jury demand has been timely made.

No party has demanded a jury trial.

11. The names of the attorneys who will appear on behalf of the parties at the management conference (the appearing attorney must be an attorney of record and have full authority to bind the client).

For Plaintiffs - Dale F. Saran, Esq., Brandon Johnson, Esq., Jerri Ward, Esq.

For Defendants - Zachary A. Avallone or Jody D. Lowenstein.

12. Whether the parties jointly consent to trial before a magistrate judge.

The parties do not unanimously consent to a United States Magistrate Judge presiding over a trial in this matter.

13. Any other matters that counsel deem appropriate for inclusion in the joint conference report or that deserve the special attention of the Court at the management conference.

None.

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CERTIFICATE OF SERVICE

This is to certify that on this 28th day of June, 2023, the foregoing Joint Report was filed using the CM/ECF system.

/s/ Brandon Johnson
Brandon Johnson